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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO |
|---|----------------|----------------------|-------------------------|-----------------|
| 09/600,732 | 07/20/2000 | GEORGES SMITS | TIENSE RAFF. | 8993 |
| 7: | 590 09/20/2002 | | | |
| NORMAN P SOLOWAY HAYES SOLOWAY HENNESSEY GROSSMAN & HAGE 175 CANAL STREET MANCHESTER, NH 03101 | | | EXAMINER | |
| | | | CHUNDURU, SURYAPRABHA | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1637 | 1.0 |
| | | | DATE MAILED: 09/20/2002 | 12 |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Application No. | Applicant(s) | | | | |
|---|---|---|---|--|--|--|--|
| | | 09/600,732 | SMITS ET AL. | | | | |
| | Office Action Summary | Examiner | Art Unit | | | | |
| | | Suryaprabha Chunduru | 1637 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address | | | | | | | |
| Period for Reply | | | | | | | |
| THE I - Exter after - If the - If NO - Failu - Any rearne | ORTENED STATUTORY PERIOD FOR REPLY MAILING DATE OF THIS COMMUNICATION, asions of time may be available under the provisions of 37 CFR 1.1: SIX (6) MONTHS from the mailing date of this communication period for reply specified above is less than thirty (30) days, a reply period for reply is specified above, the maximum statutory period vier to reply within the set or extended period for reply will, by statute eply received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b). | 36(a). In no event, however, may a repl y within the statutory minimum of thirty (will apply and will expire SIX (6) MONTH , cause the application to become ABAN | ly be timely filed 30) days will be considered timely. IS from the mailing date of this communication. NDONED (35 U.S.C. § 133). | | | | |
| Status | | | | | | | |
| 1)[\subseteq | Responsive to communication(s) filed on <u>05 J</u> | | | | | | |
| 2a)⊠ | · | is action is non-final. | | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | | |
| Dispositi | on of Claims | ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, | | | | | |
| 4) Claim(s) 29-64 is/are pending in the application. | | | | | | | |
| | 4a) Of the above claim(s) 50-64 is/are withdrawn from consideration. | | | | | | |
| 5) | Claim(s) is/are allowed. | | | | | | |
| 6)⊠ | 6)⊠ Claim(s) <u>29-49</u> is/are rejected. | | | | | | |
| 7) | Claim(s) is/are objected to. | | | | | | |
| | Claim(s) are subject to restriction and/or | r election requirement. | | | | | |
| | on Papers | | | | | | |
| 9) The specification is objected to by the Examiner. | | | | | | | |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. | | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). 11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner. | | | | | | | |
| 11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action. | | | | | | | |
| 12) The oath or declaration is objected to by the Examiner. | | | | | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | | | | | |
| 13) ★ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | | | |
| a)⊠ All b)□ Some * c)□ None of: | | | | | | | |
| , - | 1. Certified copies of the priority documents have been received. | | | | | | |
| | 2. Certified copies of the priority documents have been received in Application No | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). | | | | | | | |
| a) ☐ The translation of the foreign language provisional application has been received. 15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | | | | | | |
| Attachmen | t(s) | | | | | | |
| 2) Notice | e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449) Paper No(s) | 5) Notice of Info | mmary (PTO-413) Paper No(s) ormal Patent Application (PTO-152) | | | | |

Art Unit: 1637

DETAILED ACTION

1. Applicants' response to the office action and amendment (Paper No. 11) filed on July 5, 2002 has been entered.

Response to Arguments

- 2. Applicant's response to the office action (Paper No.11) is fully considered and deemed persuasive in part.
- 3. The rejection made under 35 U.S.C. 112 second paragraph in the previous office action is withdrawn herein in view of the applicants' amendment (Paper No.11).
- 4. The following is the rejection made in the previous office action under 35 U.S.C. 103(a):

Claims 29-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wim Van Den Ende et al. (Plant Physiol. Vol. 149: 43-50, 1996) and in view of Van Loo et al. (USPN. 5,660,872).

Wim Van Den Ende et al. teach a process for synthesizing fructan (inulin) from chicory roots wherein Wim Van Den Ende et al. disclsose that (i) the source material for the process are roots of chicory grown in appropriate regions and processed under proper climatological temperature which has not triggered fructan exohydroxylase (FEH) in chicory roots (see page 44, column 1, paragraphs 1-4, page 47, column 1, paragraph 2); (ii) chicory roots were grown for a period of at least 150 days- 180 days and the period selected from periods ranging from June 1, to December 1 (see page 44, paragraph 4); (iii) inulin was obtained with a standard grade chicory insulin with degree of polymerization (DP) ranging from 6-13 (see page 44, column 2, paragraph 1, and page 45, column 1, paragraph 1-3). However, Wim Van Den Ende et al. did not teach

Art Unit: 1637

obtaining low sugar standard grade or high performance grade chicory inulin with DP ranging from at least 10-20.

Van Loo et al. teach a method for producing inulin free with low molecular weight polysacharrides (sugars) wherein Van loo et al. disclose that the method comprises isolation of inulin from chicory roots with hot water to obtain aqueous solution of inulin, purification of inulin followed by concentrating the inulin solution by partial removal of water (see column 11, lines 47-62); the method also comprises obtaining inulin free of mono-and disacharrides, drying inulin to a particulate form (see column 12, lines 1-67, column 13, lines 1-17). Van Loo et al. further discloses obtaining inulin free of low molecular weight polysacharrides with DP greater than 5 (column 5, lines 5-44).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to modify a process for synthesizing chicory inulin as taught by Wim Van Den Ende et al. with the method of obtaining chicory inulin as taught by Van Loo et al. to achieve expected advantage of developing a process for manufacturing chicory inulin from chicory roots because Wim Van Den Ende et al. states that "seasonal changes in the biochemistry of fructan storing organs has been largely focused on the examination of changes in the stored carbohydrates. The observed changes in carbohydrate concentrations five-fold increase in fructose concentration) very well correlate with a breakdown of high DP fructans. The shift from high DP fructans from low DP fructans could be due to the action of FFT using low molecular weight carbohydrates as acceptors (see page 47, column 2, paragraph 2, and page 48, column 2, paragraph 2). One alternative form of obtaining high DP fructan, expressly motivated by Van Loo et al. is to reduce low molecular weight sugars in fructan, to provide

Art Unit: 1637

improved nutritional value of inulin. An ordinary practitioner would have been motivated to combine the method of Wim Van Den Ende et al with the method of Van Loo et al. in order to achieve the expected advantage of developing an improved process of preparing chicory inulin.

Response to Arguments:

Applicant's arguments with respect to the rejection made under 35 U.S.C. 103(a) to claims 29-49 have been considered and are found not persuasive. Applicants' particular argument that the prior art does not provide cultivating chicory outside conventional growing period and does not teach that FEH activity is responsible for fructose (inulin) production. This argument was fully considered and found not persuasive because First, Prior art teaches growing periods climatic conditions including non conventional periods June 1 to December 1, which comprises frost conditions) to cultivate chicory inulin and also showed FEH as one of the enzymes responsible for Fructose production. Second, chicory inulin production related to the FEH activity is an inherent property of chicory plants. Moreover, Applicants did not recite any limitation for inulin production under non conventional growing periods. Further, optimization of conditions for mere improvement over exisiting processes has no patentable value. In recent court decisions, In re Cruciferous Sprout Patent Litig., 168 F. Supp. 2d at 540, 60 USPQ2d at 1762, it was concluded that "merely describing unexpected beneficial results of a known process does not entitle plantiffs to patent that process". Id. at 538, 60 USPQ2d at 1760. Thus, a "plant (broccoli sprouts), long well known in nature and cultivated and eaten by humans for decades [cannot] be patented merely on the basis of a recent realization that the plant has always had some heretofore unknown but naturally occurring beneficial feature". Id. at 537, 60 USPQ2d at 1759. Thus in the instant invention, mere improvement of known process of growing conditions

Art Unit: 1637

and enzyme activities, which trigger chicory inulin production does not qualify the improved process to be of any unexpected result.

Further, selection of specific growing conditions represents routine optimization with regard to production of chicory inulin, which routine optimization parameters are explicitly recognized in Wim Van Den Ende et al. As noted in *In re Aller*, 105 USPQ 233 at 235, more particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. Routine optimization is not considered inventive and no evidence has been presented that the probe or primer selection performed was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art.

Further, Applicants argue that the prior art teaches away from the instant invenetion and does not render the pending claims 29-49 obvious. In response to applicant's argument that there is no suggestion, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071. 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir.1992). In this case, specific motivation is provided in the rejection above, which notes that an ordinary practitioner is motivated to develop an improved process to obtain chicory inulin with a change in degree of polymerization would be prima facie obvious based on the method taught by Van Loo et al. Therefore the rejection under U.S.C. 103(a) is maintained herein.

Page 6

Application/Control Number: 09/600,732

Art Unit: 1637

Conclusion

No Claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and - for After Final communications.

Art Unit: 1637

Page 7

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Suryaprabha Chunduru

September 10, 2002

JEFFREY FREDMAN PRIMARY EXAMINER